AJIC commentary

Developing a broader approach to management of infection control breaches in health care settings

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Our experiences with health departments and health care facilities suggest that questions surrounding instrument reprocessing errors and other infection control breaches are becoming increasingly common. We describe an approach to management of these incidents that focuses on risk of bloodborne pathogen transmission and the role of public health and other stakeholders to inform patient notification and testing decisions. (Am J Infect Control 2008;36:685-90.)

Instrument reprocessing errors and other infection control breaches in health care settings can present unique challenges for health care professionals and public health officials, particularly in the absence of known disease transmission.[1-4] In many of these situations, the major challenge is determining whether patient notification and testing for bloodborne pathogens (eg, hepatitis C virus [HCV], hepatitis B virus [HBV] and human immunodeficiency virus [HIV]) is required. Widespread patient notifications can be resource- and labor intensive and are not without potential harms to patients notified. In some circumstances, it can also be difficult to discern the roles and responsibilities of public health versus health care facilities and providers in the management of a breach.

We propose a qualitative approach to infection control breaches in the absence of documented disease transmission to distinguish situations that clearly warrant notification and testing for bloodborne pathogens—and thus have a clear public health role—from those that involve uncertain or hypothetical risk. Additionally, we encourage collaboration among provider organizations, infection control experts, patient advocates, public health officials, ethicists, and other key partners to develop consensus-based strategies for management of infection control breaches. As part of the increasing movement toward transparency in health care, providers have been encouraged to openly communicate harmful medical errors to patients.[5] Given potentially evolving attitudes toward patient safety and error disclosures, the merits of patient notification for infection control breaches that involve uncertain or hypothetical risk of harm should be considered.

The initial assessment of an infection control breach can include an estimation of risk from the independent probabilities of events necessary for disease transmission,[1] but the accuracy of such risk calculation methods is not known. We favor a more qualitative strategy, particularly with respect to risk of bloodborne pathogen transmission. Our suggested approach is outlined in the Appendix and the accompanying text. The evaluation of an infection control breach should be influenced by 2 critical distinctions: (1) whether bloodborne pathogen (eg, HCV, HBV, and/or HIV) transmission was possible (vs only bacteria or other nonbloodborne microbes) and (2) whether the breach involved a demonstrated or suspected high-risk practice (category A, Appendix) or was one that posed a lower risk of bloodborne pathogen transmission (category B, Appendix). These distinctions should be made early to help guide subsequent decisions. A severe breach that involved a gross error in aseptic practice usually warrants patient notification and testing.

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A less severe breach might warrant disclosure to patients without a recommendation for testing. The nature of the infection control breach and circumstances that surround it—along with input from key stakeholders, including public health—should inform decisions regarding patient notification and testing.

Assessing the health risks from a disinfection or sterilization error requires knowledgeable infection control staff and other personnel who can make technical and ethical judgments in an impartial manner that supports patients' best interests. Not all health care settings have such personnel. For example, many endoscopy clinics and ambulatory surgical centers function independently of hospitals and lack formal infection control programs. Public health officials often can assist with evaluating infection control breaches and assessing risks to patients. There are other reasons to engage public health agencies and health departments early in the process. Inappropriate practices or faulty materials implicated in a breach can extend to other health care facilities. Additionally, public health surveillance information and rapid health alert notification mechanisms are frequently helpful for case finding. Because category A breaches entail a serious and potentially widespread threat to patient safety, the management of these breaches should involve public health. Health care facilities and infection control professionals are also encouraged to engage public health in the assessment of category B breaches and corresponding discussions surrounding notification because decisions can be more difficult and subjective for this category of breaches.

The strategy described in the Appendix focuses on notification and testing for bloodborne pathogens because they are often the most challenging aspects of managing an infection control lapse. The possibility of bacterial pathogen transmission might require notification to heighten awareness, make testing and treatment recommendations, or identify cases. Although many of these same issues hold true for viral bloodborne pathogens, patient testing, counseling, and result notification are substantially more emotionally charged and can have a life-altering impact. Notification of possible exposure to serious and stigmatizing diseases can cause considerable anxiety, especially when prolonged follow-up testing is needed. The ramifications of these and other considerations in the decision-making process should not be minimized.

Effective communication is an essential component of notification. A sample patient notification letter (Fig 1) and press release (Fig 2) are provided. Communication materials should (1) use nontechnical language, (2) use qualitative interpretations of risk, and (3) include explicit recommendations that are consistent with the risk messages. Available preliminary information, such as whether or not any adverse events have been identified among exposed individuals, should be incorporated. If available, contextual information should be communicated, eg, if bacterial and/or bloodborne viral infections have never been transmitted in the setting of similar breaches, this information may provide a more meaningful understanding of risk than a numeric probability. Notifications should include guidance on testing along with supporting rationale. For situations that involve a serious infection control breach (eg, reuse of injection equipment) or where there is evidence to suggest that infections might have occurred, dedicated efforts to identify and test exposed individuals are warranted. Again, public health officials should be involved to assist with case finding, development of communication messages, planning for testing and counseling, and responding to inquiries from the public or media.

Date

Dear ___(Patient Name)_____,

The _____ health department and the _____ clinic are investigating an incident involving improper cleaning of colonoscopes at this clinic between January 1, 2007 and March 3, 2007. Although the problem has been corrected, we are contacting patients who might have been exposed to notify them.

You are being contacted because you may have undergone a colonoscopy procedure at this clinic involving a colonoscope that was improperly cleaned. We are in the process of contacting all patients who underwent this procedure at the clinic and their healthcare providers. Thus far, there has been no evidence of any infections in patients who were exposed to improperly cleaned colonoscopes.

Multiple steps are needed to process a colonoscope between uses, including cleaning several parts of the equipment and rinsing it with a disinfectant. When performed correctly, these steps remove germs from the equipment. One part of this colonoscope, the biopsy channel, was not properly cleaned out with a brush before it was placed into a machine to be disinfected. Some germs could have remained on the equipment as a result of this error. However, this type of error has not been shown to cause serious infections such as hepatitis C, hepatitis B, or HIV in the past. We believe there is only a very small chance that you could have been exposed to hepatitis C virus, hepatitis B virus, or HIVfrom this error.We do not recommend that you be tested for any of these infections.

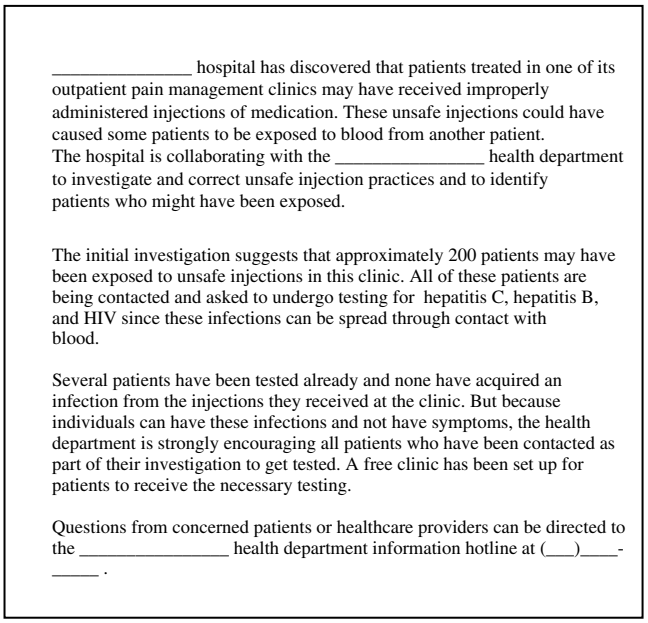
However, if you have concerns or would like to be tested, we encourage you to discuss this with your healthcare provider. We understand that you or your healthcare provider may have additional questions or concerns. To help answer questions, we have set up a telephone information hotline.

The information hotline may be reached by calling: (___)___-_____

Signed,

Fig 1. Sample patient notification letter.

Deficiencies in endoscope reprocessing are often the impetus for patient notifications.[1] Endoscope reprocessing entails a complex series of steps, including cleaning of lumen and channels, with opportunities for error at each step. The extent to which a lapse in one step might impact the overall equipment disinfection or sterilization is not well understood. Failures to adhere to endoscope reprocessing guidelines have been associated with outbreaks of bacterial infections.[6,7] However, none of the occasional reports of HBV or HCV infection associated with currently used



_____ hospital has discovered that patients treated in one of its outpatient pain management clinics may have received improperly administered injections of medication. These unsafe injections could have caused some patients to be exposed to blood from another patient. The hospital is collaborating with the _____ health department to investigate and correct unsafe injection practices and to identify patients who might have been exposed.

The initial investigation suggests that approximately 200 patients may have been exposed to unsafe injections in this clinic. All of these patients are being contacted and asked to undergo testing for hepatitis C, hepatitis B, and HIV since these infections can be spread through contact with blood.

Several patients have been tested already and none have acquired an infection from the injections they received at the clinic. But because individuals can have these infections and not have symptoms, the health department is strongly encouraging all patients who have been contacted as part of their investigation to get tested. A free clinic has been set up for patients to receive the necessary testing.

Questions from concerned patients or healthcare providers can be directed to the _____ health department information hotline at (___)____-_____ .

Fig 2. Sample press release.

gastrointestinal endoscopes have convincingly shown that the endoscope itself was the source of infection.[6,8] Instead, contamination of parenternal medications, a well-documented, yet underrecognized source of HBV and HCV transmission, was determined to be the cause of several endoscopy outbreaks and was either implicated or overlooked in the remaining reports.[6,8-11]

Available evidence suggests that the risks of bloodborne virus transmission from endoscopes that have been appropriately cleaned but have not undergone high-level disinfection are minimal.[6,12-14] Breaches in endoscope reprocessing often warrant disclosure in the form of patient notifications to heighten awareness, promote transparency in health care, and solicit reporting of possible infections; but the cumulative evidence to support HBV, HCV, or HIV testing recommendations in many of these situations is presently lacking. This is an area that needs more attention from professional organizations, medical equipment manufacturers, and public health officials to explore the appropriate responses to different types of instrument processing deficiencies.

New information and results of notification and testing activities should continue to fuel discussions surrounding risk from various types of instrument reprocessing failures. Because these types of incidents may be underreported in the literature, a centralized mechanism to track the occurrence and management of such incidents could provide much needed data to inform future decisions. In the absence of a formal surveillance mechanism, health care facilities, infection control professionals, and others who participate in patient notifications are encouraged to share results of these experiences.

Patient notification and testing efforts can involve difficult decisions and demand considerable resources from health care systems, health departments, and individual providers. The decision to pursue such actions should take into consideration potential benefits and harms to exposed individuals and should involve parties that can evaluate the situation objectively. The subject of patient disclosure in the setting of harmful medical errors has received national attention, as evidenced by the establishment of National Quality Forum standards for disclosing unanticipated outcomes to patients.[5] Although disclosure of medical errors in the absence of demonstrated harm is not addressed, some of the key elements of safe practice for disclosure likely translate to patient notifications resulting from infection control lapses. Patient safety experts should examine how best to approach patient notification in the setting of uncertain risk and consider criteria that could be used to make patient notification decisions. Discussions will also be needed among other stakeholders—including patient advocates, public health authorities, and ethicists—to refine appropriate risk assessment and risk communication strategies and to further define roles and responsibilities of various stakeholders in responding to an infection control breach.

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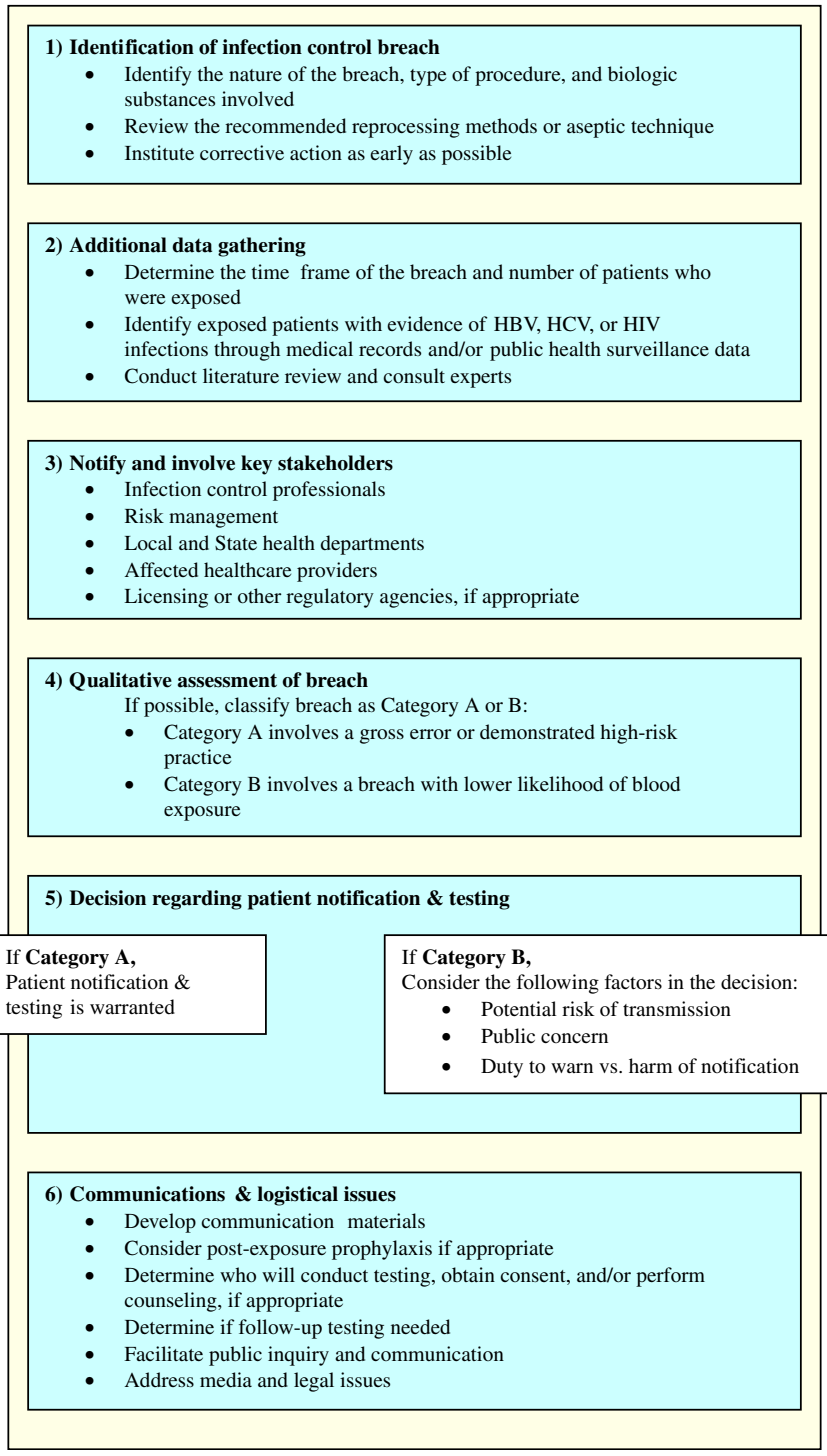
APPENDIX

Approach to an infection control breach with potential risk of bloodborne pathogen transmission assumes no known cases of bloodborne pathogen transmission as a result of the breach. If cases of bloodborne pathogen transmission from the breach are identified or suspected, a more detailed epidemiologic and laboratory investigation is warranted (not described here).

(1) Identification of infection control breach. Depending on the procedure(s), device(s), or practice(s) involved, an infection control breach may result in exposure to body fluids, tissues, or other biologic substances. The types of potentially infectious substances that could have been harbored on the contaminated instrument or device should be determined. The body surfaces or spaces (eg, mucosal membranes, solid organs or tissues, blood vessels) of exposed patients expected to come in contact with the contaminated device should also be identified. Recommendations for safe injection practices and handling of injectable medications are provided in the Standard Precautions section of the Healthcare Infection Control Practices Advisory Committee Guideline for Isolation Precautions.[15] For breaches involving an instrument or device, the manufacturer's instructions for use and recommended reprocessing methods should be reviewed and the degree to which the breach deviated from these recommendations should be determined. The nature of the breach should be assessed relative to recommended practice to understand better the extent of the breach and its potential impact on overall disinfection and sterilization or aseptic technique. For example, the evaluation should include whether key steps in reprocessing of a device were completely omitted or performed but in a suboptimal manner. Direct observation of practices that may have led to the breach should be conducted along with interviews of involved health care staff regarding their practices. It should be noted that observed practices may not reflect procedures at the time of the breach, and fear of retaliation may reduce the reliability of staff interviews in certain situations. Records of health care equipment disinfection procedures may be available to provide specific information on reprocessing methods that were followed. If a breach appears to be ongoing, procedures should be halted until a plan can be implemented to correct the infection control lapse. Once implemented, the plan of action should be rapidly assessed to determine whether the expected changes have occurred.

(2) Additional data gathering. The time frame during which the breach occurred should be determined based on staff interviews and review of instrument reprocessing, procedure, or employee records. The exposure time frame may correspond to the dates of employment of a particular health care provider whose individual practices are in question, the dates a specific procedure was performed, or the period of time during which there was a known breach as indicated by staff interviews or reprocessing records. After discerning the likely onset and duration of the breach, an attempt should be made to determine which patients were exposed to the procedure or practices impacted by it. If available, the individual patient-level bloodborne pathogen infection status should be examined. The list of affected patients can be cross-referenced against public health surveillance case reports and medical records reviewed to identify new HCV, HBV, or HIV infections that may have resulted from the exposure. Evidence of liver transaminase elevations from medical chart reviews is potentially useful in identifying patients with undiagnosed HBV or HCV infections. These activities might also be used to identify previously infected patients who could have served as a source for transmission. However, it should be noted that many exposed patients might never have been tested for bloodborne pathogens prior to the exposure.

(3) Notify and involve key stakeholders. Key partners will vary depending on the situation but should



be identified and engaged as early as possible. Parties to consider involving include the following: infection control professionals and hospital epidemiologists from the involved facilities, representatives of facility risk-management teams, affected state and local health departments, affected health care providers, and licensing or other regulatory agencies if appropriate. Occasional infection control breaches have been reported in the context of professional misconduct or substance abuse by health care providers. Such factors might influence transmission or complicate an investigation.

(4) Qualitative assessment of breach. Based on the nature of the breach, its deviation from recommended practices, and additional information gathered, a qualitative assessment of the breach should be made. ''Category A'' errors correspond to gross mistakes in

infection control practices, typically with identifiable risk. The risk assessment is based on documented bloodborne pathogen transmission in association with similar practices in the past or the observed or very high likelihood of blood exposure as a result of the breach. Examples of category A errors include (a) reuse of needles or syringes between patients and (b) reuse of contaminated syringes to access multidose medication vials or intravenous fluid bags. ''Category B'' errors correspond to breaches of infection control where the likelihood of blood exposure resulting from the breach is uncertain but thought to be less than would occur with a category A breach. Examples of category B errors include (a) colonoscope reprocessing performed with incorrect disinfectant solutions or those performed with a shorter duration than is recommended by the manufacturer and (b) reprocessing and reuse of biopsy needles that were intended for single use. Individuals and health care facilities that are called on to make these assessments are encouraged to solicit input from experts and stakeholders.

(5) Decision regarding patient notification and testing. For category A breaches, patient notification and testing usually is warranted. In these breaches, an identifiable or significant risk of bloodborne pathogen transmission exists and should be considered to outweigh the potential harms of patient notification and testing. For category B breaches, the decision to notify and/or test patients should be based on a number of factors including the information gathered and assessment of the breach and should involve the key stakeholders identified. Public concern and perceived risk in the community or among exposed individuals may also be factors and should be addressed regardless of decisions for or against patient testing. If a decision is made to test for bloodborne pathogens in the context of an infection control breach, testing for HBV, HCV, and HIV typically should be offered. In some situations, a decision might be made to disclose an error in reprocessing or infection control practices without a recommendation for testing. Although notification without a recommendation for testing might be interpreted as inconsistent or potentially confusing, it can also be a valid approach if stakeholders feel that disclosure is warranted regardless of risk and that patients should be empowered to make their own decisions regarding testing.

(6) Communications and logistical issues. Ideally, a consensus should be reached among stakeholders regarding notification decisions, and a uniform message should be conveyed. The key partners should agree on a method of notification and identify the party primarily responsible for notifying patients. When possible, patient laboratory testing and/or reimbursement for the testing should be arranged. Public health departments should be aware of the considerable financial and personnel resources that might be required for extensive patient notifications as well as the associated opportunity costs. Widespread patient notification and testing might also preclude investigation into test results. Particularly if no clustering by exposure date/time exists among patients who test positive, it is unlikely that the source of identified infections (ie, whether related to the infection control breach) could be determined. In large notification situations, patients and providers should be aware that the primary objective is to identify potential infections, not determine the source. Several other logistical issues should be considered and addressed in conjunction with the decision-making process. If the nature and timing of the breach warrant it, postexposure prophylaxis for HIV and HBV should be considered and delivered rapidly to consenting patients. This should be performed in accordance with Centers for Disease Control and Prevention recommendations.[16,17] Serologic tests should adhere to Centers for Disease Control and Prevention guidelines for HBV, HCV, and HIV.[16-18] Follow-up testing may be warranted for patients whose exposure occured within the last 4-6 months. Public inquiry and communication of public health messages should be facilitated through telephone hotlines, Internet Web postings, press releases, direct patient mailings, or other means. Potential media and legal issues should be anticipated.